K130718

APR 16 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92

Submitter Details

PeerMedical Ltd.
2 Hatochen St., POB 3161
Business and Industrial Park (North), Caesarea, 38900, Israel
Tel: +972 4 6327731, Fax: +972 4 6327734
Date prepared: March 13, 2013
Submission Contact: Tamar Fuerst PeerMedical Ltd Caesarea, 38900, Israel.

Device Details

Proprietary Name:	PeerScope System (Model H)
Common Name:	Colonoscope and accessories, flexible / rigid
Classification Name	Endoscope accessories, 21 CFR 876.1500
Product Code:	FDF (colonoscope and accessories, flexible/rigid)
Committee/Panel:	Gastroenterology/Urology
Device Class:	II

Reason for 510(k) Submission: Change in Technology

Identification of Legally Marketed Predicate Devices

PeerScope System –K#120289 - Manufactured by PeerMedical Ltd.

Device Description

The PeerScope system Model H is a GI platform for diagnostic visualization and therapeutic intervention of the lower digestive tract. The PeerScope system Model H is a modification of the legally marketed (K 120289) PeerScope system Model B (the predicate device).
The system consists of endoscopic Main Control Unit (MCU H) and of the PeerScope CS colonoscope, enabling physicians to view a high resolution wide field of view of up to 300°.
The system is labeled for use in healthcare facilities / hospitals for adult patients.

Intended use and indications for Use

The PeerScope System is intended for diagnostic visualization of the digestive tract.
The system also provides access for therapeutic interventions using standard endoscopy tools. The PeerScope System is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients.
The PeerScope System consists of PeerMedical camera heads, endoscopes, video system, light source and other ancillary equipment.

Technological characteristics

The MCU Model H video processor incorporates the following additional features compared to the predicate device:

Category	Predicate Device PeerScope system Model B K120289	Subject Device PeerScope system Model H	Impact of the differences on device performance
Video resolution	Standard definition	High definition	Both designs utilize industry accepted standard for video resolution.
User interface	Hardware based	Hardware based and Software based (GUI)	Both designs utilize industry accepted standard for User interface.
I/O Communication Ports	Not Included	Included	I/O Communication Ports are an industry accepted standard for basic communication which were not included in the MCU B design.
Video Signal Output	Analog	Analog and Digital	Both designs utilize industry accepted standard for Video Signal Output.
Video Signal Input	Not Included	Included	Video Signal Input is an industry accepted standard which was not included in the MCU B design.
Monitor Display Configuration options	Triple	Triple and Single	Single Monitor Display Configuration is an additional alternative/option for Display Configuration.

Based on the results of verification, validation and performance testing, the impact of the above differences is insignificant in terms of the device safety and effectiveness for the device intended use.

K130718

Performance data

Bench data:
Risk analysis was conducted in accordance with ISO 14971. Design verification tests and their acceptance criteria were identified, performed and met.

Software validation was carried out in accordance with FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)".

Reprocessing validation was carried out in accordance with FDA Guidance Document "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Draft Guidance (May 2011)".

Device safety and performance were verified by PeerMedical and accredited third party laboratories.

The following standards were used / relied upon for testing:

AAMI / ANSI ES 60601-1:2005/(R) 2012 and C1:2009/(R) 2012
AAMI / ANSI ES60601-1:2005/A1:2012
IEC 60601-1-2:2007
IEC 60601-2-18 Edition 3.0 2009-08
IEC 62304:2006
ISO 10993:2009 Part #1
ISO 10993:2009 Part #5
ISO 10993:2010 Part #10
ISO 10993:2007 Part #12
ISO 8600-1 Second edition 2005-05-01
ISO 8600-3 First edition 1997-07-01
ISO 8600-4 First edition 1997-07-01
ISO 8600-6 First edition 2005-03-15
ASTM E 1837- 96 (reapproved 2007)

Usability Data:
Device Usability was carried out by means of testing within a clinical environment in a US medical center by seven experienced GI physicians.

The conclusions drawn from the bench and usability tests demonstrate that the device meets its specifications, and supports a determination that the device is at least as safe and effective for its intended use as the predicate device.

K130718

Substantial Equivalence

The above presented data demonstrate that:

a. The predicate device the PeerScope System Model B (K120289) is legally marketed.
b. The PeerScope System Model H and the predicate device have the same intended use.
c. The PeerScope System Model H does not raise different questions of safety and effectiveness.
d. The data provided support a determination that the PeerScope System Model H is at least as safe and effective for its intended use as the predicate device.

Conclusion: It is the opinion of PeerMedical that the PeerScope system Model H is substantially equivalent to the predicate device, in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 16, 2013

PeerMedical Ltd.
% Ms. Tamar Fuerst
RA Manager
2 Hatochen Street, Business Industrial Park (North)
CAESAREA
ISRAEL 38900

Re: K130718
Trade/Device Name: PeerScope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: March 18, 2013
Received: March 19, 2013

Dear Ms. Fuerst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130718

Device Name: PeerScope System

Indications For Use:
The PeerScope System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The PeerScope System is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients. The PeerScope System consists of PeerMedical camera heads, endoscopes, video system, light source and other ancillary equipment.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130718